DECLARATION OF CONFORMITY

FULL QUALITY ASSURANCE SYSTEM

Product Name: Endiscope

Model Numbers: 10-2020, 10-2021, 10-2022, 10-2023, 10-3020, 10-3021, 10-3022

GMDN Code: Spinal endoscopic-access system [32579]

Device Classification: IIa, Rule 7

Applied Standards:

- ISO 8600-1:2015
- ISO 8600-3:1997/Amd 1:2003
- ISO 8600-4:2014
- ISO 8600-5:2005
- ISO 8600-6:2005
- AAMI / ANSI ST81:2004/(R)2010
- IEC 60601-2-18:2009
- ISO 10993-1:2009/(R)2013
- EN ISO 15223-1:2016
- ISO 13485:2016
- EN ISO 14971:2012
- EN 1041:2008+A1:2013

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INTERTEK SEMKO AB
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EC Certificate Number: 41316578-03

Serial Number:

This declaration of conformity is issued under sole responsibility of the manufacturer. The object of the declaration described above is in conformity with the relevant Community Harmonization Legislation. I hereby declare that the products specified above meet the requirements set forth in LVFS 2003:11 and Council Directive MDD 93/42/EEC, MDD Annex II, excluding Section 4 and conform to the identified harmonized standards. In addition, the object of the declaration described above is in conformity with RoHS Directive 2011/65/EU (RoHS 2) of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. [RoHS]

Alan Ellman, CEO

April 21, 2020
Date